K024249

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

FEB 2 1 2003

A. Device Name

Proprietary Name

TERUMO® SURGUARD™ Safety Syringe or similar proprietary name

Classification Name

Piston Syringe with Single Lumen Needle (880.5860) with antistick

Classification: Class II 80FMF & 80MEG

Common Name

Hypodermic syringe with safety sheath or Syringe with needle protection device

B. Intended Use

The Surguard™ Safety Syringe is a device intended for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. The syringe will also be used to withdraw medication from vials. This device is intended for insulin, allergy, or general use injections. Additionally, after withdrawing the needle from the patient, the safety feature can be manually activated to cover the needle to minimize the risk of accidental needlestick.

C. Device Description

The Surguard Safety Syringe consists of a graduated hypodermic syringe barrel with a permanently affixed needle (also called cannula) and an integrated safety feature component, which is permanently attached at the top of the syringe barrel close to the needle. The safety feature component can swivel to allow users additional flexibility in positioning the syringe and bevel for use. The locking mechanisms are located within the body of the sheath and at the collar that attaches to the top of the syringe barrel.

The syringe portion is the same as Terumo's Insulin and Terumo's Allergy/General Syringe that are the subject of K882083 and K980796 respectively. No changes were made to the syringes other than a minor modification to outside of the barrel to allow for secure attachment of the safety feature.

The syringe is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The syringe will also be used to withdraw medication from vials. The syringe barrel will be graduated in insulin units for use with insulin or in cc/ml units for allergy or general use. The allergy/ general use syringe is offered with an intradermal bevel for intradermal injections and a regular bevel typically used for subcutaneous injections. The general use syringe has a regular bevel, which can be used for common injections such as intradermal, intramuscular, or subcutaneous. The insulin syringe will contain orange-colored needle cap and the allergy/general use syringe will contain a non-colored (white) cap.

The safety sheath is activated after syringe use and prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath against a firm surface, thereby engaging the needle into the sheath. The user will visually confirm the needle is locked beneath the locking tab.

D. Substantial Equivalence

The Surguard Safety Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Insulin Syringe (K822083), the Terumo Allergy Syringe (K980796), and the Portex Needle-Pro® Syringe (K011925).

E. Principle of Operation and Technology

The Terumo Surguard Safety Syringe, the Terumo Insulin and Allergy/General Syringes, and the Portex Needle Pro Syringe are all operated manually.

F. Materials

The materials used for the syringe portion of the Surguard Safety Syringe are identical to the materials used for the Terumo Insulin and Allergy syringes. The material selected for the safety feature is the same type of material used for the Portex Needle Pro. Differences in materials between the Surguard Safety Syringe and the Portex Needle Pro (K011925) raise no new issues of safety and effectiveness.

G. Specifications

Product Code	Cap Color	Description
SG10M2913	Orange	1cc Insulin Syringe with 29g x ½" needle
SG05M2913	Orange	1/2cc Insulin Syringe with 29g x ½" needle
SG30M2913	Orange	3/10cc Insulin Syringe with 29g x ½" needle
SG10M2813	Orange	1cc Insulin Syringe with 28g x ½" needle
SG05M2813	Orange	1/2cc Insulin Syringe with 28g x ½" needle
SG10A2713T	White (No color)	1cc Allergy Syringe with 27g x ½" needle– Multi-piece tray
SG10A2613T	White (No color)	1cc Allergy Syringe with 26g x ½" needle– Multi-piece tray
SG10A2710IDT	White (No color)	1cc Allergy Syringe with 27g x 3/8" Intradermal needle– Multi-piece tray
SG10A2610IDT	White (No color)	1cc Allergy Syringe with 26g x 3/8" Intradermal needle– Multi-piece tray
SG01D2516	White (No color)	1cc (General) Syringe with 25g x 5/8" needle– Low deadspace
SG01D2713	White (No color)	1cc (General) Syringe with 27g x ½" needle– Low Deadspace
SG01D2610ID	White (No color)	1cc (General) Syringe with 26 x 3/8" Intradermal needle

H. Performance

The following tests were performed on the Surguard Safety Syringe:

- Activation Force
- Deactivation Force
- Sheath Penetration Force
- Sheath Removal Force
- Collar Removal Force
- Sheath Swivel Force
- Hinge Integrity
- Residual Volume
- Simulated Use Study

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

The performance of the Surguard Safety Syringe submitted in this 510k is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Insulin Syringe (K822083), the Terumo Allergy Syringe (K980796), and the Portex Needle-Pro® Syringe (K011925).

I. Additional Safety Information

Manufacturing controls include visual, functional, and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137-1994 Medical Devices – Validation and Routine Control of Radiation Sterilization. The Surguard Safety Syringe is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The Terumo Surguard Safety Syringe is classified as Externally Communicating Device, Blood Path Indirect, Limited Duration of Contact (< 24 hr). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

J. Conclusion

The Surguard Safety Syringe is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Terumo Insulin Syringe (K822083), the Terumo Allergy Syringe (K980796), and the Portex Needle-Pro® Syringe (K011925).

Differences between the devices do not raise any significant issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

Date Prepared:

Prepared By: Barbara Smith
Sr. Regulatory Affairs Specialist

Prepared For: Terumo Medical Corporation
125 Blue Ball Rd.
Elkton, MD 21921
Phone: 410-392-7241
Fax: 410-398-6079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1 2003

Ms. Barbara Smith
Senior Regulatory Specialist
Terumo Medical Corporation
Regulatory Affairs Department
125 Blue Ball Road
Elkton, Maryland 21921

Re: K024249
Trade/Device Name: TERUMO® SURGUARD™ Safety Syringe
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF
Dated: December 20, 2002
Received: December 23, 2002

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

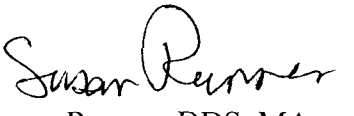
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: TERUMO® SURGUARD™ Safety Syringe

Indications For Use:

The Surguard™ Safety Syringe is a device intended for the manual aspiration of fluids, and for the injection of fluids into parts of the body below the surface of the skin. The syringe will also be used to withdraw medication from vials. This device is intended for insulin, allergy, or general use injections. Additionally, after withdrawing the needle from the patient, the safety feature can be manually activated to cover the needle to minimize the risk of accidental needlestick.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Tatiana Cecconi

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024249